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Nestle HealthCare Nutrition 12 Vreeland Road, 2nd Floor, Box 697 Florham Park, NJ 07932				
EXAMINER				
KOSAR, AARON J				
ART UNIT		PAPER NUMBER		
1651				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdepartment@rd.nestle.com  
athena.pretory@rd.nestle.com

### Office Action Summary

**Application No.**

10/516,600

**Applicant(s)**

AURIO ET AL.

**Examiner**

AARON J. KOSAR

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22, 24-30, 32, 33, 35-38 and 45-59 is/are pending in the application.
- 4a) Of the above claim(s) 29, 38 and 45-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22, 24-28, 30, 32, 33 and 35-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

Applicant's amendment and argument filed February 26, 2009 in response to the non-final rejection and filed July 16, 2009 in response to the notice of non-compliant amendment, are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Applicant has amended the claims by introducing new claims 55-59 and canceling claims 19-21 and 39-44. Since Applicant has received an action on the merits for the elected invention of Group III (a composition of matter), then new claims 56-59, which are drawn to a method of administering a composition, have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 22, 24-30, 32, 33, 35-38, and 45-59 are pending, of which claims 29, 38, and 45-59 are withdrawn as being directed towards non-elected inventions/species.

Claims 22, 24-28, 30, 32, 33, and 35-37 have been examined on the merits.

Please note, grounds of rejection presented herein which are directed to species other than the elected species (i.e. guar gum, collagen, a metabolic syndrome) are presented to further demonstrate the non-allowability of the generic invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22, 26-28, 30, and 35-37 remain rejected under 35 U.S.C. 102(b) as being anticipated by Jaussan (AU 9873118 A).

A composition comprising a fiber and a protein are claimed, including the respective protein and fiber species thereof wherein the composition has a viscosity of less than about 500 mPa·s. is claimed. Additionally, the dependent claims are drawn to proportions/ratios of components, the rheological properties (viscosity) of the composition, and product form thereof.

Jaussan anticipates the claims by teaching a diabetes-treating composition comprising a milk, whey, casein, soy, rice, pea, and/or oat protein (page 4, lines 28-33)(a moderately-hydrolyzed, viscosity-lowering protein) and a guar gum, xanthan gum, gum Arabic, pectin, and/or  $\beta$ -glucan (pg. 5-6, page 3)(a viscous soluble fiber). Jaussan also teaches the composition containing casein and soy protein in combination with soluble fiber having a viscosity of less than about 500 mPa·s (1 Pa·s = 1 kg/m·s), including a composition having a viscosity of less than 0.04 kg/m·s and 0.023 kg/m·s (40 and 23 mPa·s, respectively), wherein the soluble fiber contains pectin or gum arabic (claim 8).

Regarding claim 28, Jaussan further teaches providing the composition as a drink by teaching blending the composition with water to form a liquid composition (pages 6-7),

providing the composition as a food/dietary supplement, and formulating the composition to have a viscosity e.g. of 0.023 Pa·s which is about the claimed viscosity of the instantly-claimed drink. Jaussan teaches a composition having the 1.0 g soluble fiber (0.5g pectin or gum arabic per 100ml sample (page 4, line 26; examples 1 and 2) and 3.8 g per 100 mL casein:soy protein (1:1) (examples 1 and 2). Jaussan thus teaches a composition comprising a soluble fiber: (soy) protein ratio of between 0.01:1 and 20:1, by teaching a ratio of 0.26:1 (w/w) ( $0.5:1.9 = 0.26:1$ ).

Though Jaussan is silent regarding the elected species of collagen, Jaussan is applicable in demonstrating the unpatentability of the generic invention over the prior art. Therefore the reference is deemed to anticipate the instant claims above.

#### ***Response to Arguments***

Applicant has argued that Jaussan does not teach inulin absence, the properties of the proteins as viscosity-lowering proteins, and also teaches that the composition of Jaussan increases stomach/small intestine contents' viscosity when the composition is administered.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., inulin absence in the composition, viscosity of the composition in the stomach and small intestine, a method of using/administering the composition to the stomach/small intestine) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that Jaussan does not teach combining the ingredients for the purpose of lowering viscosity (and lowering viscosity relative to a viscosity-lowering-

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protein free composition), although Jaussan recognizes the combination of ingredients and formulation to obtain a product capable of effecting increased stomach-content viscosity, the fact that Applicant has recognized another advantage (viscosity-lowering within the composition) which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Please note, since the prior art composition has the same recited chemical components therein versus the as-claimed composition and a viscosity which is about the claimed viscosity, then viscosity-lowering, though not expressly recited by Jaussan, would be intrinsic to the protein-containing composition of Jaussan and thus still meets the instant claims.

Claims 22, 25-27, 30, 33, 35, and 36 are/remain rejected under 35 U.S.C. 102(b) as being anticipated by Laughlin (U.S. Patent No. 5,470,839).

Laughlin teaches an oral/enteric composition comprising guar (or gum arabic) (a viscous soluble fiber) and casein (a moderately hydrolyzed viscosity-lowering protein) in the ratio of 0.15:1 (w/w) ( $7/45 = 0.15/1$ ) (whole document, e.g. example, column 6-7). Laughlin also teaches the composition has a viscosity of 90 cPs max (less than about 500 mPa·s) (e.g. example, column 6-7).

Although Laughlin does not recite a relative viscosity versus a protein-absent composition or an intended effect of viscosity-lowering of the protein upon the soluble fiber therein, since Laughlin teaches the identical components and a viscosity of 90 cPs max (less than about 500 mPa·s), then the compositions of Laughlin (and the components therein) which are inseparable from their inherently properties/functions would thus necessarily function as instantly claimed. (see also MPEP 2112.01(II)).

Therefore the reference is deemed to anticipate the instant claims above.

#### ***Response to Arguments***

Applicant has argued that Laughlin does not teach that the protein is a moderately hydrolyzed viscosity-lowering protein or that the amount should be sufficient to reduce the viscosity of the composition.

In response to applicant's argument that Laughlin does not teach providing moderately hydrolyzed protein for the purpose of lowering viscosity in the composition, the fact that Applicant has recognized another advantage (viscosity-lowering within the composition) which

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would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Please note, since the prior art composition has the same recited chemical components, including the species casein or whey (moderately-hydrolyzed proteins), and since a compound is inseparable from its chemical properties (e.g. viscosity lowering), then although the properties are not expressly recited by Laughlin, would be inherent to the protein-containing composition of Laughlin and thus the prior art still meets the instant claims.

Claims 22-28, 30, 32, 33, and 35-37 are/remain rejected under 35 U.S.C. 102(b) as being anticipated by Ohta (EP 0323510).

Ohta teaches a composition comprising a protein and fiber, including casein and carageenan in liquid form (page 5; figures 5 and 8). Ohta teaches that liquid form is maintained in contact with gastric juices when protein in the composition is below half as that of the fiber component (abstract; page 5, pgh.1-2). Ohta teaches modifying the ratios of fiber:protein or 0.1:1 through 2:1 (example 5, page 12) . Ohta also teaches modifying pH and temperature to affect viscosity less than about 500 mPa·s by teaching effecting a viscosity below 100 cPs (100 cPs = 100 mPa·s;), including less than 50 cPs (50 mPa·s)(figure 1). Ohta also teaches the formulation of the composition for food for diabetic/glucose-intolerant patients (page 18).

Therefore the reference is deemed to anticipate the instant claims above.

### ***Response to Arguments***

Applicant has argued that Ohta does not teach that the protein is intended to be used in the composition by functioning as a moderately-hydrolyzed, viscosity-lowering protein in the composition.

In response to applicant's argument that the protein has use as a moderately-hydrolyzed, viscosity-lowering protein in the composition which is not taught by Ohta, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Since Ohta teaches a composition comprising the same chemical components as instantly-claimed and because Ohta teaches the composition having a viscosity in the as-claimed range (e.g. 100 mPa·s), then the prior art proteins would inherently lower viscosity in the composition. Please note, although Ohta teaches additionally a method of using the composition by reducing temperature or pH or contacting with gastric juice, Ohta still teaches the composition prior to said temperature/pH lowering and thus said composition of Ohta would inherently contains a hydrolyzed viscosity-lowering protein (e.g. contains casein) as instantly-claimed.

Also, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., treating the composition with reduced temperature, pH, gastric juice) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claims 22, 26-28, 30, and 35-37 are/remain rejected under 35 U.S.C. 102(b) as being anticipated by Heath (GB 2021948 A).

Heath teaches a composition comprising guar gum (a viscous soluble fiber) and a protein coating including the use of casein, soy, or gluten (a moderately-hydrolyzed, viscosity-lowering protein) in the coating (column 1; claims).

Although Heath does not expressly recite the composition as having 500 mPa·s viscosity at room temperature or that the coating protein functions as a viscosity-lowering protein, this would be an inherent to said casein, soy, or gluten and thus to said composition containing said proteins. Also, since Heath teaches the composition having the claimed components, then the composition of Heath would also inherently have about the as-claimed viscosity.

Therefore the reference is deemed to anticipate the instant claims above

### ***Response to Arguments***

Applicant has argued that Heath does not teach a composition which is less viscous than the viscosity-reducing protein free composition and that Heath does not teach moderate hydrolysis of the protein.

In response to Applicant's arguments that the as-claimed composition has properties not taught by Heath, this is not persuasive, because Applicant's appreciation of a property (viscosity-lowering), though not recited by Heath would be intrinsic to the composition of Heath and for example because Applicant has not provided objective evidence which would preclude the composition of Heath, absent the protein, from having a higher viscosity.

In response to Applicant's argument that Heath does not teach moderately-hydrolyzed protein, this is not persuasive, because the specification does not provide a measure by which degrees of hydrolysis may be classified and thus "moderately hydrolyzed proteins" absent evidence to the contrary embraces all proteins, which are in some way moderately hydrolyzed.

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

*This application currently names **joint inventors**. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).*

Claims 22, 24-28, 30, 32, 33, and 35-37 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jaussan, Laughlin, Ohta, or Heath (of record).

The cited references each disclose a composition comprising components (including for example beta-glucan, whey protein, etc. and combinations thereof) which appear to be identical to the presently claimed composition since the compositions contain the same minimally-

required chemical compounds (e.g. protein and fiber and the recited species and combinations thereof). Consequently, the claimed composition appears to be anticipated by the references.

In the alternative, even if the compositions (with respect to a particular viscosity/viscosity range, or “about” a particular percent or viscosity) is not identical to the referenced composition, with regard to some unidentified characteristics, the differences between that which is claimed and that which is disclosed, is so slight that the referenced composition is likely to inherently possess the same characteristics of the claimed composition, particularly in view of the similar characteristics which they have been shown to share (e.g. the component chemical features in combination in the composition). Thus, the claimed composition would have been obvious to those of ordinary skill in the art within the meaning of 35 USC § 103(a).

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Please note, since the Office does not have the facilities for examining and comparing Applicants’ composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980), and “as a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.” *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

**Claim Rejections - 35 USC § 103**

The relevant portion of 35 USC 103(s) is as presented above.

Claims 22, 26-28, 30, and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell (U.S. Patent No. 6,210,686).

Bell teaches a dietary cholesterol level effecting composition (column 3, lines 50-62) (composition for oral administration) formulated to provide an amount of fiber (comprising one or more viscous soluble fiber).

Bell does not teach the many instantly-claimed combinations of fiber-and-protein, including, including combinations of  $\beta$ -glucan with whey protein, egg, or soy protein.

It would have been obvious to have provided the fiber-containing composition of Bell with viscous soluble fibers and protein because Bell teaches combining the composition with one or a combination of ingredients, including fiber and "any suitable protein" (column 5, lines 34-60). It would have been obvious to have provided the composition with  $\beta$ -glucan and with whey protein, egg, or soy protein because Bell teaches that yeast  $\beta$ -glucan has advantages in the composition over the other fiber forms (column 3, lines 50-53) and because protein, including whey protein, egg, soy protein, and mixtures thereof may be incorporated into the composition (column 5, lines 34-41). One would have been motivated to have provided  $\beta$ -glucan and whey protein, egg, and/or soy protein to the composition because Bell teaches that the dietary/oral composition containing yeast beta-glucan has advantages in the composition over other fibers (column 3) and is more palatable (e.g. tasteless, odorless; column 4) than oat-derived beta-glucan

and because Bell teaches that the selection of dietary supplement ingredients including protein is a mere matter of judicious choice by the artisan skilled in the art of supplement formulation/design (column 5, lines 56-58).

Bell is relied upon for the reasons discussed above. If not expressly taught by Bell, based upon the overall beneficial teaching provided by this reference with respect to fibers and proteins in the composition, and with respect to providing a variety of product forms including beverages and puddings, in the manner disclosed therein, the adjustments of particular conventional working conditions (e.g., determining one or more suitable amount of fiber and/or protein in which to provide said composition, determining the proportions and amounts of ingredients to obtain about 500 mPa·s viscosity/lowered-viscosity in the composition), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 22, 24-28, 30, 32, 33, and 35-36 are/remain rejected under 35 U.S.C. 103(b) as being anticipated by Gunter (U.S. Patent No. 3,889,007) or Wittwer (U.S. Patent No. 4,478,658)

The general teachings of the claims are above.

GUNTER and WITTWER teach the components collagen and guar gum (e.g. Gunter, claims 1 and 8; e.g. Wittwer, claims 6, 8). Whereas Gunter and Wittwer do not teach a composition comprising the combination of guar gum and collagen, it would have been obvious to have provided a composition comprising both of the components, because collagen and guar gum were known individually at the time of the instant invention to a person of ordinary skill in the art of food/edible compositions. One would have been motivated to have combined guar gum and collagen because Gunter teaches that the components are useful for the same purpose, as food organic binders and because Wittwer teaches that the components are useful as film-forming materials wherein "the film forming material may be selected from the group consisting of gelatin, collagen, cellulose, cellulose ethers and esters, modified and unmodified starches, substituted and unsubstituted polyvinyl acetate, polymers and co-polymers of acrylic acid and methacrylic acid, and their salts and esters, natural gums such as gum arabic, gum tragacanth, locust bean gum, guar gum, and mixtures of the above" (Wittwer, column 4/5). One would have had a reasonable expectation of success in making a composition comprising guar gum and collagen because success merely requires the contacting of known components in a known and predictable manner, and especially in the absence of objective evidence to the contrary or which would preclude the components from providing a composition to the extent instantly claimed. (see also MPEP § 2144.06).

Gunter is relied upon for the reasons discussed above. If not expressly taught by Gunter, based upon the overall beneficial teaching provided by this reference with respect the use of collagen/guar gum and the general benefit of optimizing the components of the food composition (which would directly or indirectly optimize the collagen/guar gum concentrations) in the manner disclosed therein - Gunter is deemed to have about the requisite features to the extent claimed or, in the alternative - the adjustments of particular conventional working conditions (e.g., determining one or more suitable concentration ranges in which to obtain a composition), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

#### ***Response to Arguments***

Applicant has argued that Gunter and Wittwer do not teach the advantages that are achievable in the use of the composition (e.g. Remarks page 14) and that Gunter does not teach a moderately-hydrolyzed protein capable of functioning to lower viscosity, versus the protein-free composition.

In response to applicant's argument that Gunter does not teach the advantages that are achievable in the use of the composition, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to

patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, since the as-claimed composition recites a fiber, e.g. guar gum, and a moderately hydrolyzed protein, e.g. collagen, and because the prior art renders obvious compositions comprising the claimed combinations, including the structurally identical composition of guar gum and collagen (a viscous soluble fiber and a moderately hydrolyzed viscosity-lowering protein, respectively), the properties of which would be inherent to the chemicals therein, then the composition comprising the same combination of guar gum and collagen as the as-claimed composition would intrinsically have the recited properties. (see also MPEP § 2112.01).

In response to applicant's argument that Gunter and Wittwer do not teach a protein capable of functioning to lower viscosity (versus the protein-free composition), the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In the instant case, since Gunter and Wittwer teach that the components were known and useful in the art for the equivalent purpose as argued for the reasons of record, then it would have been obvious to have combined the components in the composition wherein, although silent regarding viscosity lowering effects or comparative viscosity to the protein free analogous composition, the composition of Gunter or Wittwer would have intrinsically had the as-claimed viscosity of "about less than 500 mPa·s" and thus is still rendered obvious by the references.

In response to Applicant's argument that the prior art does not teach a "moderately hydrolyzed" protein, this is not persuasive because hydrolyzed proteins in the composition of Gunter and Wittwer include proteins which are "about" the instantly disclosed molecular weight range (specification, page 4, lines 3-5) and because the "hydrolyzed proteins" broadly and reasonably include proteins in which the hydrolysis "may occur *in vivo*, i.e. after ingestion of the composition of the invention" (specification, page 4, lines 8-10).

Claims 22, 24-28, 30, 32, 33, and 35-37 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nakayama *et al* (US 6,287,623, of record).

Nakayama teaches a drink composition comprising a protein and gelling agent (a protein and a viscous soluble fiber) (whole document, e.g. claims 9, 19, and 29), including a composition comprising casein and agar (a viscosity-lowering protein and a viscous soluble fiber)(e.g. example 8). Nakayama teaches the food and drink composition having a viscosity of not greater than 20 centipoise (20 cPs = 20 mPa·s) (e.g. claims 9, 19, 29). Nakayama also teaches providing the composition with gelling agents, including guar gum; varying/adding amounts of gelling agent; and using one or more proteins, including collagen/gelatin (e.g. columns 3, 6, and 7). Nakayama also teaches modifying the composition based on the desired end product. In particular, Nakayama teaches (a) optimizing the protein content to effect the desired smoothness of the product, including optimizing protein to be between 0.1 to 10% by weight and further optimizing to between 0.5 and 7% protein by weight (e.g. column 4, ¶4; column 6, ¶6); (b) optimizing the amount of gelling agent, including 0.1-1.0% (agar) by weight (e.g. column 6, ¶ 2); (c) direct measurement or, as needed to reduce viscosity in more viscous samples, dispersion with (500mL) water of a gelling-agent-containing drink compositions (e.g. column 7, ¶1-3); and (d) a ratio of fiber (gelling agent) to viscosity-lowering protein (protein) of 0.06:1 (see e.g. column 14, example 8: casein/agar = 0.26/3.6 = 0.06/1).

Nakayama does not teach the elected species combination of collagen and guar gum; however, it would have been obvious to a person of ordinary skill in the art at the time of the invention to have made a collagen-and-guar gum composition from the teachings of Nakayama..

It would have been *prima facie* obvious to add to or substitute the protein/casein and gelling agent/agar in the liquid nutrient composition (e.g. example 8) with collagen and guar gum, because Nakayama teaches that any one or more proteins which may be used in food and drink may be used as the protein source, including collagen and/or casein (column 3, ¶1). Regarding the gelling agent, it would have been *prima facie* obvious to combine or substitute the agar in the composition with a gelling agent including guar gum, because Nakayama teaches that any suitable edible gelling agent may be used as the gelling agent source, including guar gum and/or agar (column 6, ¶3). One would have been motivated to add/substitute collagen and guar gum, because Nakayama teaches collagen/guar gum from a finite list of species of proteins/gelling agents, which said proteins/agents are recognized as equivalent protein/gelling agent sources and because Nakayama teaches that any one or more of the species of protein/agent may be used in the invention. One would have had a reasonable expectation of success in combining the compositions comprising collagen/guar gum, because Nakayama teaches compositions comprising protein and gelling agent and because, absent evidence to the contrary, the success of the combination of the two components, including collagen and guar gum depends merely upon contacting the components. (see also MPEP § 2144.06)

Regarding the elected species (guar gum-to-collagen) ratios and viscosity of guar gum-and-collagen comprising compositions, though Nakayama does not expressly teach the ratio of guar gum:collagen or the viscosity of the combination with this species, Nakayama teaches the general benefit of varying the composition components which includes the benefit of enhancing the texture, taste, and feel of the compositions wherein varying the component proportions would necessarily affect the viscosity of the composition. Nakayama further teaches and appreciates the

benefit of producing a product which has a viscosity less than 20 cPs has a desirable smoothness (e.g. column 7, lines 15-30) and effecting a variety of viscosities (e.g. liquids, jellies, etc) in product preparations (e.g. examples 1-8)..

Thus, Nakayama is relied upon for the reasons discussed above. If not expressly taught by Nakayama, based upon the overall beneficial teaching provided by this reference with respect reagent/component ratios and viscosity in the manner disclosed therein, the adjustments of particular conventional working conditions (e.g., determining the optimal ratios of components to effect a desirable viscosity), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Please note, since the Office does not have the facilities for examining and comparing Applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980), and "as a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products

and make physical comparisons therewith.” *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

***Response to Arguments***

Applicant has also argued that Nakayama does not teach a moderately hydrolyzed protein and does not teach a viscosity-lowering property of the protein.

In response to Applicant's argument that Nakayama does not teach a moderately hydrolyzed protein, this is not found to be persuasive, because Nakayama teaches that the protein, includes any processed protein, including hydrolyzed proteins (e.g. col 3, lines 9-12).

In response to Applicant's argument that Nakayama does not teach viscosity-lowering (and a lower viscosity relative to a protein-absent composition), since Nakayama teaches providing the composition with a protein, including a hydrolyzed protein/collagen and also teaches providing the composition as a drink and/or having 20 mPa·s viscosity (less than 500 mPa·s), as argued above, then the composition of the Nakayama still renders obvious the composition of the claims as-drafted.

No claims are allowed.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Kosar/  
Examiner, Art Unit 1651

/Christopher R. Tate  
Primary Examiner, Art Unit 1655